

AMENDMENTS TO THE CLAIMS

1. (Withdrawn) A method of screening intraductal breast fluid for one or more breast disease marker, comprising the steps of contacting the breast with a mechanical intraductal fluid aspiration device, activating the device to apply peristaltic compression and suction to the breast during a period of non lactation to remove intraductal breast fluid, and screening the fluid for breast disease markers.

2. (Withdrawn) A method of screening intraductal breast fluid as in Claim 1, further comprising the step of applying heat from the device to the breast.

3. (Withdrawn) An intraductal breast fluid screening device, comprising:
a tissue contacting surface defining a first concavity for receiving a breast and a second concavity for receiving a nipple;

a driver, for imparting compressive force on at least a portion of the tissue contacting surface defining the first concavity;

a vacuum conduit in communication with the second concavity; and

a sample collector in communication with the second concavity.

4. (Withdrawn) An intraductal breast fluid aspiration device as in Claim 3, wherein the driver imparts peristaltic compressive force on the tissue contacting surface.

5. (Withdrawn) An intraductal breast fluid aspiration device as in Claim 3, further comprising a heat source thermally coupled to the tissue contacting surface.

6. (Withdrawn) An intraductal breast fluid aspiration device as in Claim 3, wherein the driver comprises a motor.

7. (Withdrawn) An intraductal breast fluid aspiration device as in Claim 3, wherein the driver comprises at least one expandable chamber.

8. (Withdrawn) An intraductal breast fluid aspiration device as in Claim 7, wherein the chamber is defined within a flexible tube.

9. (Withdrawn) An intraductal breast fluid aspiration device as in Claim 3, further comprising a vacuum source in communication with the vacuum conduit.

10. (Withdrawn) An intraductal breast fluid aspiration device as in Claim 3, wherein the sample collector comprises a collection patch.

11. (Withdrawn) An intraductal breast fluid aspiration device as in Claim 3, wherein the collector is removable from the aspiration device.

12. (Withdrawn) An intraductal breast fluid aspiration device as in Claim 10, wherein the sample collection patch comprises a binding system for binding at least one analyte of interest in the breast fluid.

13. (Withdrawn) An intraductal breast fluid aspiration device as in Claim 12, wherein the binding system comprises a monoclonal antibody.

14. (Withdrawn) An intraductal breast fluid aspiration device as in Claim 3, further comprising a microprocessor for controlling the driver.

15. (Withdrawn) An intraductal breast fluid aspiration device as in Claim 3, further comprising a housing, wherein the tissue contacting surface is removably carried by the housing.

16. (Withdrawn) A portable, self contained, intraductal fluid screening device, comprising:

a housing;

a breast interface on the housing;

at least one cell and cell fragment collector in communication with the breast interface;

a vacuum source in communication with the interface;

a compression driver coupled to the interface; and

at least one control on the housing for controlling operation of the aspiration device.

17. (Withdrawn) A portable, self contained, intraductal fluid aspiration device as in Claim 16, wherein the interface is removably connected to the housing.

18. (Withdrawn) A portable, self contained, intraductal fluid aspiration device as in Claim 16, comprising a fluid reservoir in communication with the interface.

19. (Withdrawn) A portable, self contained, intraductal fluid aspiration device as in Claim 18, wherein the fluid reservoir is removably attached to the housing.

20. (Withdrawn) A portable, self contained, intraductal fluid aspiration device as in Claim 16, further comprising a heating element in thermal communication with the interface.

21. (Withdrawn) A portable, self contained, intraductal fluid aspiration device as in Claim 16, further comprising an ultrasonic transducer in communication with the interface.

22. (Withdrawn) An intraductal fluid aspiration device, comprising:

a control unit;

a power head;
a flexible control line connecting the power head to the control unit;
a disposable user interface removably attached to the power head;
a vacuum source in the control unit, in communication with the user interface through the control line;

a heat source in thermal communication with the user interface; and
a compression cycle generator in force transmitting contact with the user interface.

23. (Withdrawn) An intraductal fluid aspiration device as in Claim 22, further comprising a central processing unit in the control unit for controlling the delivery of heat, compression and suction through the user interface.

24. (Withdrawn) A method of increasing yield in a breast ductal aspiration, comprising the steps of:

providing a carrier;
introducing the carrier under pressure retrograde into the duct; and
recovering the carrier from the duct, using compression, heat and suction.

25. (Withdrawn) A method as in Claim 24, wherein the introducing the carrier step comprises directing a stream of the carrier at the external opening of the duct.

26. (Withdrawn) A method as in Claim 24, wherein the recovering the carrier step is assisted by administering oxytocin.

27. (Withdrawn) A method as in Claim 24, further comprising the step of clearing the duct in the vicinity of the external opening to facilitate fluid flow, prior to the introducing the carrier step.

28. (Withdrawn) A method of enhancing the transport of intraductal indicium of a physiological condition for diagnostic analysis, comprising the steps of:

transductally introducing a carrier under pressure retrograde into a breast duct; and
retrieving the carrier from the duct for diagnostic analysis.

29. (Withdrawn) A method as in Claim 28, wherein the carrier comprises a component for enhancing transport of the indicium from the duct.

30. (Withdrawn) A method as in Claim 28, wherein the indicium comprises a metabolite.

31. (Withdrawn) A method as in Claim 28, wherein the indicium comprises carcinomatous or dysplastic cells.

32. (Withdrawn) A method as in Claim 28, wherein the retrieving the carrier step comprises aspirating the carrier under suction and compression.

33. (Currently Amended) A method of screening for breast cancer in a patient, comprising the steps of:

a¹ providing a patient having at least one breast duct with an external opening thereon;

directing a stream of carrier fluid under pressure into the opening to introduce a volume of carrier fluid into the duct;

removing carrier fluid from the duct through the external opening by applying compression, suction, and heat to the breast; and

screening the removed carrier fluid for at least one ~~indiciu~~^{indiciu} ~~of a physiological condition~~
breast cancer marker.

34. (Cancelled) A method as in Claim 33, wherein the removing carrier fluid step is assisted by the application of suction to the external opening of the duct.

35. (Original) A method as in Claim 33, wherein the screening step comprises screening for cytologically abnormal cells.

36. (Withdrawn) A method of introducing a therapeutic species into a breast duct, comprising the steps of:

identifying a patient having at least one breast duct with an external opening thereon;

providing a media comprising a carrier and at least one therapeutic species;

directing a stream of the media at the external opening to the duct to introduce the media into the duct.

37. (Withdrawn) A method as in Claim 36, wherein the carrier comprises a liquid.

38. (Withdrawn) A method as in Claim 36, further comprising the step of manipulating the duct to enhance transport of the media within the duct.

39. (Withdrawn) A method as in Claim 36, further comprising the step of applying suction to the external opening to remove media from the duct.

a² 40. (Currently Amended) A method as in Claim 33, wherein the ~~indiciu~~^{indiciu} ~~comprises~~
a breast cancer marker is associated with at least one condition selected from the group consisting of tumorigenesis, tumor growth, neovascularization, and cancer invasion.

41. (New) A method as in Claim 33, further comprising the step of manipulating the duct to enhance transport of the carrier fluid within the duct.

42. (New) A method as in Claim 33, wherein the compressive force comprises peristaltic compressive force.

43. (New) A method as in Claim 33, wherein the step of removing carrier fluid from the duct through the external opening, by applying compression, suction, and heat to the breast comprises contacting the breast with an intraductal breast fluid screening device, the device comprising a tissue contacting surface defining a first concavity for receiving a breast and a second concavity for receiving a nipple; a driver, for imparting compressive force on at least a portion of the tissue contacting surface defining the first concavity; and a vacuum conduit in communication with the second concavity.

44. (New) A method as in Claim 43, wherein the intraductal breast fluid aspiration device further comprises a heat source thermally coupled to the tissue contacting surface.

45. (New) A method as in Claim 43, wherein the intraductal breast fluid aspiration device further comprises a vacuum source in communication with the vacuum conduit.

46. (New) A method as in Claim 43, further comprising a sample collector.

47. (New) A method as in Claim 43, wherein the collector is removably carried by the aspiration device.

48. (New) A method as in Claim 47, wherein the sample collector comprises a binding system for binding at least one analyte of interest in the breast fluid.

49. (New) A method as in Claim 48, wherein the binding system comprises a monoclonal antibody.

50. (New) A method as in Claim 43, wherein the intraductal breast fluid aspiration device further comprises a housing, wherein the tissue contacting surface is removably carried by the housing, a breast interface on the housing, and at least one cell and cell fragment collector in communication with the breast interface.

51. (New) A method as in Claim 50, wherein the intraductal breast fluid aspiration device further comprises a fluid reservoir in communication with the interface.

52. (New) A method as in Claim 50, wherein the intraductal breast fluid aspiration device further comprises an ultrasonic transducer in communication with the interface.

53. (New) A method as in Claim 33, wherein the step of directing a stream of carrier fluid under pressure into the opening to introduce a volume of carrier fluid into the duct comprises transductally introducing carrier fluid.

54. (New) A method as in Claim 33, wherein the step of directing a stream of carrier fluid under pressure into the opening to introduce a volume of carrier fluid into the duct comprises percutaneously introducing carrier fluid.

55. (New) A method as in Claim 33, wherein the carrier fluid comprises a component for enhancing transport of the breast cancer marker from the duct.

56. (New) A method as in Claim 33, wherein the step of removing carrier fluid is conducted immediately after the step of directing a stream of carrier fluid under pressure into the opening.

57. (New) A method as in Claim 33, wherein the step of removing carrier fluid is conducted after the step of directing a stream of carrier fluid under pressure into the opening after a sufficient indwelling period of time to permit mobilization of carrier-soluble or carrier-transportable cells, cell components, or markers.

58. (New) A method as in Claim 33, wherein the carrier fluid comprises an aqueous solution.

a³ 59. (New) A method as in Claim 40, wherein the breast cancer marker comprises a metabolite.

60. (New) A method as in Claim 40, wherein the breast cancer marker comprises carcinomatous cells or dysplastic cells.

61. (New) A method as in Claim 40, wherein the breast cancer marker is selected from the group consisting of a protein, a peptide, a glycoprotein, a lipid, a glycolipid, and a proteolipid.
